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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,451	09/21/2001	Marc O. Schurr	06530.0276-00000	2507

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WASHINGTON, DC 20001-4413

EXAMINER
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EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

09/957,451

Applicant(s)

SCHURR ET AL.

Examiner

Darwin P. Erez

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7,120,121,124,126,127,129-132,134,135,137,138,140,142-145,147-155,157 and 164-167.

Continuation of Disposition of Claims: Claims rejected are 1,2,4,5,7,120,121,124,126,127,129-132,134,135,137,138,140,142-145,147-155,157 and 164-167.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 164-167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 164-167 recite the limitation “wherein the device is permanently implantable”, which means that the device is capable of being permanently retained in the body. However, the newly added limitation to the independent claims now recite that the first and second arms are formed of bioabsorbable materials. Therefore, it is unclear as to how a clip that is bioabsorbable is permanently implanted since it will dissolve after a period of time.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 7, 120, 121, 124, 126, 127, 129, 130, 134, 135, 137, 138, 140, 142, 143, 147-153, 157 and 164-167 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,849,019 to Yoon.

(claims 1, 120, 135 and 148) Figs. 9 and 10 of Yoon discloses a clip that is fully capable of securing a fold of tissue for treating GERD, the clip comprising:

a first arm **124**;

a second arm **126** disposed substantially opposite from each other,

wherein the first and second arms have a first end fixedly connected to each other to define an opening that is capable of receiving a fold of tissue (the clip shown in Fig. 10 is in an open position and can receive tissue),

wherein the first and second arms extend substantially in the same direction as the fold of tissue (see Figs. 9 and 10),

wherein the opening allows tissue to extend beyond a second end of the first and second arm (the clip merely compresses on any object/tissue located between the first and second arms and does not limit any tissue from extending beyond the ends 132 and 134),

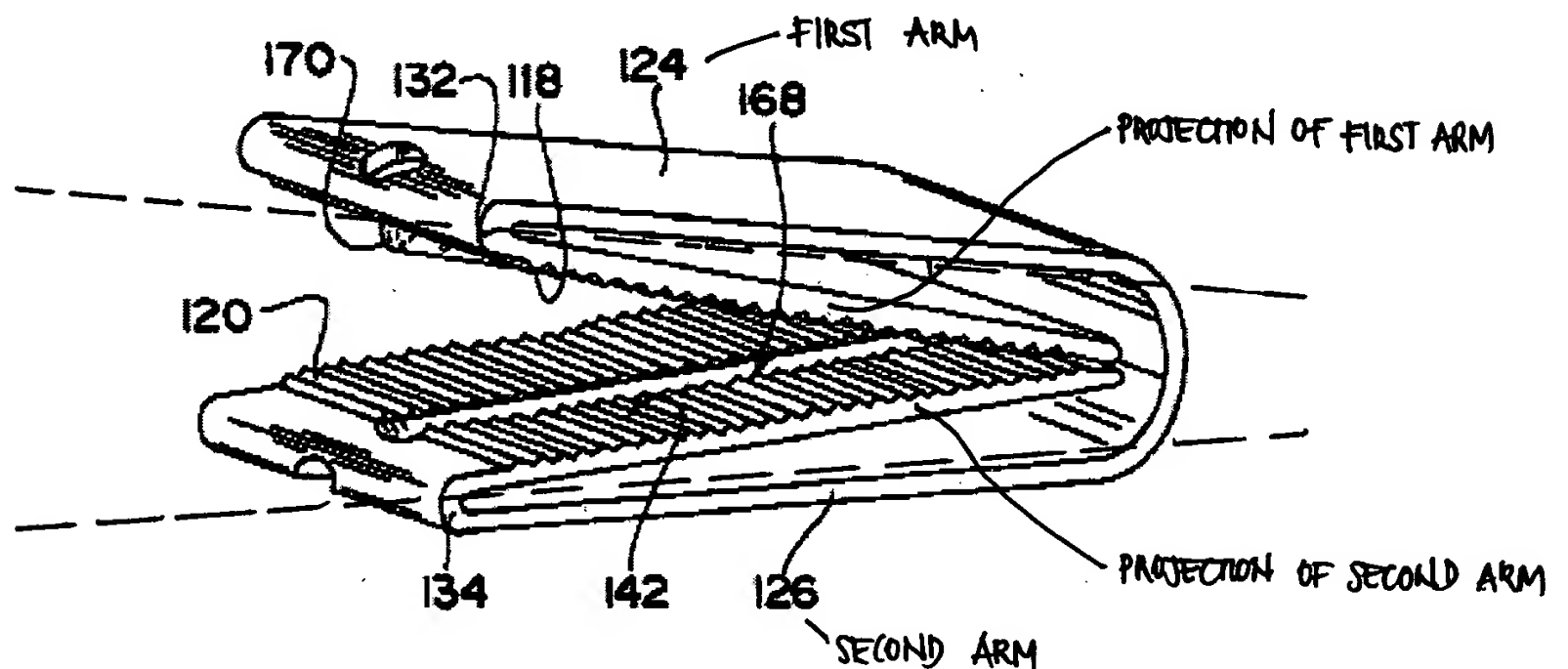
wherein the second end of the first and second arms are capable of maintaining a non-contacting relationship when in a deployed stated (when an object/tissue is located between the first and second arms),

wherein the first and second arm includes integral anchoring portions (see attached figure below) which are projections that are capable of maintaining a non-contacting relationship with the other of the first and second arms during a deployed state,

wherein the first and second arms are comprised of bioabsorbable material such that the entire clip, including the first and second arms, is capable of disintegrating in a body (col. 3, lines 40-41), and

wherein the clip is fully capable of being inserted through an esophagus.

**FIG. 10**



(claim 2) The first and second arms are fully capable of frictionally engaging an outer surface of a tissue fold.

(claim 4) The first arm and second arm each have a hole that is capable of receiving an anchoring member. It is noted that the anchoring member is not positively recited.

(claims 7, 134, 147 and 157) The first arm and second arm forms a substantially U-shaped configuration, see attached figure above.

(claim 121) The anchoring portion, as illustrated above, is fully capable of engaging a fold of tissue therebetween.

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(claims 124, 126, 127, 137, 138, 140 and 149-152) The anchoring portion comprises of two projections, one from each arm and located opposite to one another, and are in the form of a reverse angle barb (see attached figure above).

(claims 130, 143 and 153) The distal end of the first and second arms are tapered (see Figs. 9 and 10).

(claims 164-167) The clip is permanently implantable, until it is absorbed by the body. The clip could also be formed from non-bioabsorbable clips (col. 3, lines 40-41).

(claim 129 and 142) The embodiment shown in Fig. 4 also discloses all the limitations of independent claims 1 and 135, and in addition: an additional anchoring member comprising a suture.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5, 131, 132, 144, 145, 154 and 155 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon, as applied in the rejections above, and in view of US 3,032,039 to Beaty.

Yoon discloses an aperture **44** in the distal ends of the first and second arm for allowing an applicator to open the clip. Yoon is silent with regards to a tab for allowing the same function. However, Beaty discloses a clip that is similar in operation to the clip of Yoon, in that an applicator is used to open the clip. Beaty further discloses the clip having tabs **14, 16** for allowing the applicator to open said clip. Thus, the tabs of Beaty is an equivalent structure known in the art because both the tabs of Beaty and the apertures of Yoon allow an applicator to open the clip. Therefore, because these two elements were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the tabs of Beaty for the aperture of Yoon.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1, 2, 4, 5, 7, 120, 121, 124, 126, 127, 129-132, 134, 135, 137, 138, 140, 142-145, 147-155, 157 and 164-167 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has amended the independent claims to recite the limitation “wherein the first and second arms are comprised of bioabsorbable material such that the first and second arms are capable of disintegrating in a body (emphasis added)”.

The emphasized portion is the applicant's attempt to overcome the prior art of reference



to Codling. This limitation has not been previously considered and has resulted in an updated search and a new grounds of rejection.

Though the claims previously recited the first and second arms comprised of bioabsorbable material, the claims did not provide the limitation of “such that the first and second arms are capable of disintegrating in a body”. Codling did teach the first and second arms comprised of two materials: a core material that is capable of disintegrating in a body and a plating material that prevents the core from disintegrating. Therefore, it is clear that the applicant amended the claims to include “such that the first and second arms are capable of disintegrating in a body” to further limit the claim and to read over the Codling reference. Thus, the Finality of this Office action is proper under the new grounds of rejection.

### ***Conclusion***

9. As stated above, the applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

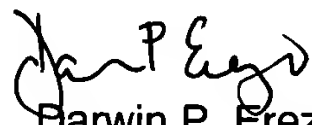
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Darwin P. Erezzo  
Examiner  
Art Unit 3731

de

  
**ANHTUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
4/14/07